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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/540,309 | 01/09/2006 | Lee Hudson | 117163.00128 | 6443 |
| 21324 7590 05/07/2008 HAHN LOESER & PARKS, LLP One GOJO Plaza Suite 300 AKRON, OH 44311-1076 | | | | |
| EXAMINER MANUEL, GEORGE C | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3762 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 05/07/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
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Office Action Summary

Application No.

10/540,309

Applicant(s)

HUDSON, LEE

Examiner

George Manuel

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/29/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 1/29/08 have been fully considered but they are not persuasive. An evoked response is the result of a sensory stimulus; however, neither the specification, nor the claims indicate what provides the sensory stimulus. Also, Fig. 1, Fig. 2 and Fig. 5 do not show or indicate what feature of the invention provides a verification of the evoked response.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the preamplifier further comprises) are not recited in the rejected claim(s). Claim 1 states, "...the preamplifiers further comprises ...". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Whigham describes a DC coupled buffer amplifier 22 with a coupling capacitor 20 which is used to block DC on the electrodes and to prevent the DC offset voltage of the amplifier 22 from being amplified. The claimed switch matrix does not appear to have an associated attribute distinguishable from the switch matrix disclosed in Whigham. The claims do not require the input signals to the differential amplifier to originate from any of the same or different leads controlled by the setting of the switch matrix.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a preamplifier system circuit, does not reasonably provide enablement for amplifying a sensed signal by the preamplifier system circuit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the pacing system of the invention commensurate in scope with these claims. Paragraph [0021] describes the claimed method for determination of the presence of an evoked response includes the steps of amplifying the sensed signal by the preamplifier system of claims 1 or 4. Claims 1 and 4 do not provide an enabling disclosure for connecting the preamplifier system to sense signals.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 12 and 19, it is unclear what is meant by observing a programmable detection time window. An evoked response signal is claimed as triggering the threshold detector; however, antecedence is provided for a plurality of threshold detectors making it unclear which is being triggered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 4, 5 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Whigham et al (US 4,821,724).

Whigham et al discloses a preamplifier system circuit in Figs. 2A and 2B. The examiner is interpreting a DC coupled buffer amplifier to comprise amplifier 22 and a switch matrix to comprise the bank of switches having 288k resistors shown in Fig. 2B. Comparator 50 provides a differential amplifier stage. It is recognized that a single amplifier is used in the embodiment of Fig. 2. However, Whigham et al teach two amplifiers could be used for a variant of the embodiment. See col.8, line 50 to col. 9, line 4.

A delta modulator also requires an amplifier and a capacitor. As far as the circuit of FIG. 2B is concerned, there is no savings in components since a delta modulator (requiring one capacitor) and a filter (requiring two capacitors and two resistors) would still require the same number of components shown in the drawing--three capacitors and two resistors. The savings is in the use of a single amplifier,

comparator 50, instead of the two which would otherwise be required—one for the delta modulator and the other for the filter. The main advantage of achieving both delta modulator and filter functions with the use of a single active device is that less power is required to operate the pacemaker.

Whigham et al show switch 46 that is capable of resetting to an analog ground.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 6-13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whigham et al (US 4,821,724).

Whigham et al show all of the claimed features except for a next stage comprising a low pass filter and a high pass filter, protection circuitry for pacing, and verifying capture

One of ordinary skill in the art would have found it obvious to substitute low and high pass filters for the bandpass filter disclosed in Whigham et al because low pass and high pass filters represent a frequency band shift for a bandpass filter.

Whigham et al show an output generator 13 that is capable of providing pacing pulses to a heart. One of ordinary skill in the art would have found it obvious to provide protection circuitry for the sensing circuitry to avoid overdriving the sensitive sensing circuitry with the pacing pulses. In addition, one of ordinary skill in the art would have found it obvious to verify the capture the heart for the pacing protocol because capture verification is a function of pacing reliability and Whigham et al teach it is an objective to provide reliable sensing of the capture of the heart.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel/
George Manuel
Primary Examiner
Art Unit: 3762